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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/848,750	05/19/2004	John Robert Tagg	512585-2001.1	4642

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FROMMER LAWRENCE & HAUG
745 FIFTH AVENUE- 10TH FL.
NEW YORK, NY 10151

EXAMINER	
KOSSON, ROSANNE	
ART UNIT	**PAPER NUMBER**
1653	

DATE MAILED: 04/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/848,750	TAGG ET AL.	
	Examiner	Art Unit	
	Rosanne Kosson	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *October 7, 2005*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *46-143* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *46-143* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 46, 48, 50, 52, 54, 56, 58, 60, 62, 64, 66, 68, 70, 72, 74, 76, 78 and 80, drawn to an isolated protein and a therapeutic composition comprising this protein, wherein the protein is an antibacterial protein from *Streptococcus salivarius* strain K12 having an N-terminal sequence of SEQ ID NO: 1, classified in class 514, subclass 17.

II. Claims 47, 49, 51, 53, 55, 57, 59, 61, 63, 65, 67, 69, 71, 73, 75, 77, 79 and 81, drawn to an isolated protein that differs from SEQ ID NO: 3 by the insertion, deletion or substitution of 1-3 amino acids and a therapeutic composition comprising this protein, classified in class 514, subclass 12.

III. Claims 82, 85, 88, 90, 92 and 142, drawn to a polynucleotide that encodes a protein from *Streptococcus salivarius* strain K12 having an N-terminal sequence of SEQ ID NO: 1 and a microorganism having a gene encoding the protein, classified in class 536, subclass 23.7.

IV. Claim 83, 87, 89, 91, 93 and 143, drawn to a polynucleotide that encodes a protein that differs from SEQ ID NO: 3 by the insertion, deletion or substitution of 1-3 amino acids and a microorganism having a gene encoding the protein, classified in class 536, subclass 23.7.

V. Claim 84 and 86-93, drawn to a polynucleotide comprising SEQ ID NO: 2 and a microorganism having a gene encoding the protein encoded by SEQ ID NO: 2, classified in class 536, subclass 23.7.

VI. Claims 94, 96, 102, 104, 110, 112, 118, 120, 126 and 128, drawn to a method of inhibiting the growth of harmful Streptococci in the upper respiratory tract of an individual, comprising administering an effective amount of a therapeutic composition comprising an antibacterial protein from *Streptococcus salivarius* strain K12 having an N-terminal sequence of SEQ ID NO: 1, classified in class 514, subclasses 17.

VII. Claims 95, 97, 103, 105, 111, 113, 119, 121, 127 and 129, drawn to a method of inhibiting the growth of harmful Streptococci in the upper respiratory tract of an individual, comprising administering an effective amount of a therapeutic composition comprising a protein that differs from SEQ ID NO: 3 by the insertion, deletion or substitution of 1-3 amino acids, classified in class 514, subclass 12.

VIII. Claims 98, 100, 106, 108, 114, 116, 122, 124, 130 and 132, drawn to a method of inhibiting the growth of harmful Streptococci in the upper respiratory tract of an individual, comprising administering an effective amount of a microorganism having genes encoding an antibacterial protein from *Streptococcus salivarius* strain K12 having an N-terminal sequence of SEQ ID NO: 1 and the protein of SEQ ID NO: 3, classified in class 424, subclass 93.44.

IX. Claims 99, 101, 107, 109, 115, 117, 123, 125, 131 and 133, drawn to a method of inhibiting the growth of harmful Streptococci in the upper respiratory tract of an individual, comprising administering an effective amount of a microorganism having genes encoding a protein that differs from SEQ ID NO: 3 by the insertion, deletion or substitution of 1-3 amino acids and the protein of SEQ ID NO: 3, classified in class 424, subclass 93.44.

X. Claim 134, drawn to a method of treating streptococcal upper respiratory tract infections, comprising administering an anti-streptococcal antibiotic and administering *Streptococcus salivarius* organism(s) that produce BLIS, classified in class 424, subclass 93.44.

XI. Claims 135 and 137, drawn to the protein of SEQ ID NO: 5, classified in class 514, subclass 13.

XII. Claim 136, drawn to a polynucleotide comprising SEQ ID NO: 4, classified in class 536, subclass 23.7.

XIII. Claim 140, drawn to a therapeutic formulation comprising two types of *Streptococcus salivarius*, one having a gene encoding an antibacterial protein from *Streptococcus salivarius* strain K12 having an N-terminal sequence of SEQ ID NO: 1, and one having a gene encoding SEQ ID NO: 5, classified in class 424, subclass 93.44.

XIV. Claim 141, drawn to a therapeutic formulation comprising two types of *Streptococcus salivarius*, one having a gene encoding a protein that differs from SEQ ID NO: 3 by the insertion, deletion or substitution of 1-3 amino acids and one having a gene encoding SEQ ID NO: 5, classified in class 424, subclass 93.44.

The inventions are distinct, each from the other because of the following reasons.

Each of the inventions of Groups I-V and XI-XIV is drawn to a separate and distinct composition. The compositions of Groups I, II and XI are drawn to different protein compositions, each protein having a different sequence. Each of the inventions of Groups III-V and XII is drawn to a different polynucleotide sequence, while each of the inventions of Groups XIII and XIV is drawn to a different microorganism, a strain of *S. salivarius* whose DNA

comprises polynucleotides not present in Groups III-V or XII. Therefore, these inventions are patentably distinct.

Each of the inventions of Groups VI-X is drawn to a separate and distinct method of treating a streptococcal upper respiratory tract infection as each method is practiced with a different composition and no one method is required for any other. Each method has different steps. Therefore, these inventions are patentably distinct.

The composition of Group I is not required for and is not used in the methods of Groups VII-X. Therefore these inventions are patentably distinct.

Groups I and VI are related as a product and method of using the product. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the composition of Group I may be used in in vitro methods to identify inhibitors and enhancers of the claimed protein(s), or the composition may be added to another food, drug or cosmetic composition to inhibit streptococcal contamination. Therefore, these inventions are patentably distinct.

The relationship of Group I to Group VI (related as a product and method of use but patentably distinct) and to Groups VII-X (not related) is analogous to the following arrangements of groups:

II vs. VII and	II vs. VI and VIII-X
III vs. VIII and	III vs. VI, VII, IX and X
IV vs. IX and	IV vs. VI-VIII and X
V vs. none and	V vs. VI-X
XI vs. none and	XI vs. VI-X

XII vs. none and XII vs. VI-X

XIII and none and XIII and VI-X

XIV and none and XIV and VI-X

Additionally, the searches for any one group are not required for and are not coextensive with the searches for any other group, thereby creating an undue burden of search and examination. The results from a search of each of these groups have different considerations with respect to the prior art. Burden lies not only in the search of U.S. patents, but also in the search for literature and foreign patents and in examination of the claim language and specification for compliance with the statutes concerning new matter, distinctness, written description and enablement. Further, the different groups have each acquired a separate status in the art, as shown in part by their different classifications.

Applicants must choose **ONE** polypeptide or **ONE** polynucleotide from among those claimed as indicated in the different groups above. Each polypeptide and each polynucleotide sequence is a distinct invention requiring separate searches. These are NOT species. Each sequence is a chemically, structurally and functionally distinct molecule. Therefore, the each of these polypeptides and each of these polynucleotides is patentably distinct.

Moreover, each sequence requires a separate set of searches. Applicants should note that searching each sequence imposes a serious search burden. Currently, there are approximately eight different databases that accompany the results of a search for one discrete amino acid or nucleic acid sequence, and each result set from a particular database must be carefully considered. Each set of prior art has its own considerations with respect to anticipation and obviousness. Hence, the search for even two different polypeptides or polynucleotides in the databases, in addition to searching the organic molecule databases, would require extensive searching and review. Therefore, these inventions are patentably distinct.

Because these inventions are distinct for the reasons given above, restriction for examination purposes as indicated is clearly proper.

Further, this application contains claims directed to the following patentably distinct species of the claimed invention. The species are as follows.

a) Applicants must choose whether the therapeutic composition of claim 56 is a medicament (claim 58), a food or drink (claim 66) or a confection (claim 72).

b) Applicants must choose whether the therapeutic composition of claim 57 is a medicament (claim 59), a food or drink (claim 67) or a confection (claim 73).

c) In claim 80, Applicants must choose whether the secondary antibacterial agent is Salivaricin A, SEQ ID NO: 5, a microorganism that expresses Salivaricin A or a microorganism that expresses SEQ ID NO: 5.

d) In claim 81, Applicants must choose whether the secondary antibacterial agent is Salivaricin A, SEQ ID NO: 5, a microorganism that expresses Salivaricin A or a microorganism that expresses SEQ ID NO: 5.

The elections in a) and c) above will be applied to claims 94, 96, 102, 104, 106 and 108.

The elections in b) and d) above will be applied to claims 95, 97, 103, 105, 107 and 109.

Applicant are required under 35 U.S.C. 121 to elect a single disclosed species in a) – d) above for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. The following claim(s) are generic: 46, 47, 80-87 and 94-101.

Applicants are advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is

allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicants should note that claims 102-105 and 110-113 depend from claims 94-97, respectively. Claims 102-105 recite the term "said microorganism," for which there is no antecedent basis. Presumably, Applicants meant the term "said protein." Claims 110-113 recite the phrase "said microorganism is a *Streptococcus salivarius* strain," for which there is no antecedent basis. Presumably the phrase "said protein is derived from a *Streptococcus salivarius* strain" is meant. Appropriate correction is required.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosanne Kosson whose telephone number is 571-272-2923. The examiner can normally be reached on Monday-Friday, 8:30-6:00, with alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber, can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Rosanne Kosson
Examiner, Art Unit 1653

rk/2006-03-28

Rosanne Kosson

JON WEBER
SUPERVISORY PATENT EXAMINER